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Reamed Interlocking Intramedullary Nailing of Open Fractures of the Tibia

[Original Articles: Fractures]

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Abstract

One hundred twelve open tibial fractures were treated by reamed interlocking nailing in 108 patients. There were 31 (28%) Grade I fractures, 38 (34%) Grade II, 23 Grade IIIA (21%), and 20 (18%) Grade III B fractures. Early amputation was performed in 2 (10%) Grade IIIB fractures for severe crushing injuries. Compartment syndrome complicated 8 (7%) fractures. Mean time to union was 29 weeks for Grade I fractures, 32 weeks for Grade II, 34 weeks for Grade IIIA, and 39 weeks for Grade IIIB. Nonunion complicated 9 (8%) fractures: 1 (3%) Grade I fracture, 2 (5%) Grade II fractures, 3 (13%) Grade IIIA fractures, and 3 (17%) Grade IIIB fractures. Deep infection complicated 4 Grade II fractures (10%) and 2 (11%) Grade IIIB fractures. Reamed locking intramedullary nailing is a safe and effective technique for management of open tibial fractures.

Interlocking intramedullary nailing is widely used for the management of closed tibial fractures.[11,17,29,35] The use of reamed nails for open tibial fractures has been viewed with disfavor.[6,21,39] Reaming is known to damage the endosteal blood supply [37] and, in conjunction with the soft tissue injury, this has been considered to be associated with an unacceptable risk of deep infection and nonunion. Despite this widely held view, published clinical data on the use of reamed intramedullary nails in the management of open tibial fractures are limited.

The current study is an assessment of the use of reamed locking nails to treat open tibial fractures. The aim of the study was to analyze the results of reamed nailing in a large series of open tibial fractures and, in particular, to document the complication rates in relation to the soft tissue injury.

MATERIALS AND METHODS

Between October 1987 and June 1993, 120 patients with 124 open tibial diaphyseal fractures were treated by reamed interlocking tibial nailing. Of the original group, 10 patients failed to return for followup. Two elderly patients died within 72 hours of admission, 1 of a serious head injury and the other of a myocardial infarction. These patients were excluded from the study group. This left 112 fractures in 108 patients. There were 84 male and 24 female patients with a mean age of 36 years (range, 16-88 years). The most common mechanism of injury was a motor vehicle accident. Twenty-three patients were motor vehicle drivers or passengers, 12 were motorcyclists, 4 were cyclists, and 34 were pedestrians. Eight patients had simple falls, and 12 patients sustained their injury during sporting activity. Work related accidents accounted for 14 cases. One fracture was the result of an assault.

The severity of open injury was classified according to Gustilo et al,[19,20] based on the initial appearance of the wound, the radiographs, and the findings during debridement. There were 31 (28%) Grade I fractures, 38 (34%) Grade II fractures, 23 Grade IIIA (21%), and 20 (18%) Grade IIIB fractures. The fracture comminution was graded using the Winquist and Hansen classification [46](Table 1). The median injury severity score [2] was 13. Thirty-one patients were multiply injured with an injury severity score of 18 or greater. All fractures were diaphyseal as defined by Müller et al.[33]

Winquist Hansen Grade	Number (%)
Spiral	8 (7)
I	23 (20)
II	30 (27)
III	32 (29)
IV	12 (11)
Segmental	7 (6)
Total	112

TABLE 1. Winquist Hansen Classification of Fracture Comminution

A standard management protocol was used in all cases. After initial clinical assessment, all patients were commenced on 1 g intravenous cephazolin (Ancef, Smithkline Beecham Pharma Inc, Oakville, Ontario, Canada) given every 8 hours and continued for 72 hours. Patients with Grade IIIB fractures were given intravenous gentamicin in addition. All the operative procedures were performed by or with the supervision of 1 of the authors. Wound debridement and nailing were done using a separate surgical setup. Ten liters of saline irrigation was used in each case. The limb was redraped once debridement and irrigation were completed.

The nailing procedure was performed with the patient in skeletal traction on a fracture table.

All fractures of the shaft were considered suitable for nailing. Fractures closer than 5 cm to the knee or 3 cm to the ankle generally were not considered feasible for intramedullary nailing. A longitudinal incision over the patellar tendon was used for nail insertion. A parapatellar approach was used to gain access to the intramedullary canal in the majority of cases. The intramedullary canal was reamed to a diameter 1 mm in excess of the selected nail diameter. Fractures were stabilized with a Grosse-Kempf interlocking tibial nail (Howmedica, East Rutherford, NJ). There were 3 9-mm nails, 5 10-mm nails, 66 11-mm nails, 25 12-mm nails, 10 13-mm nails, and 1 14-mm nail. Reflecting the nail sized used, 2 fractures were reamed to 10.5 mm, 5 to 11 mm, 63 to 12 mm, 6 to 12.5 mm, 19 to 13 mm, 2 to 13.5 mm, 10 to 14.5 mm, and 3 to 14.5 mm. Five fractures were dynamically locked. All remaining fractures in the study were statistically locked. Fractures in the proximal 1/3 or distal 1/3 had 2 locking screws inserted in the end of the nail adjacent to the fracture. The mean time from injury to the nailing procedure was 7.8 hours (range, 3-26 hours). Thirty-seven fractures were nailed more than 8 hours after the injury. The delay in almost all cases was because of time taken for patient transfers from remote areas of British Columbia province.

The compound wound was left open at the end of the procedure. No wound was closed primarily. In October 1989, the use of an antibiotic bead pouch was introduced as an adjunct to infection prophylaxis.[26] The beads were made of 1 mix of Simplex cement (Howmedica International, London, UK) loaded with 2.4 g tobramycin. The beads were sealed in the wound with an Opsite (Smith and Nephew, Hull, UK) dressing and left in situ until delayed closure was performed.

The median time to wound coverage was 5 days (range, 3-12 days). Twenty-three wounds were allowed to heal by secondary intention. Delayed primary closure was done in 60 fractures, and split skin grafting was performed in 9 fractures. Eighteen flaps were performed in Grade IIIB fractures. There were 9 soleal flaps, 5 latissimus dorsi free flaps, 3 gastrocnemius flaps, and 1 local fasciocutaneous flap. In the other 2 Grade IIIB fractures, the patients had extensive crushing of calf muscle. After serial debridements, it was judged that the functional capacity of the limbs would have been seriously impaired. A decision was made to amputate these limbs on this basis. The amputation rate for Grade IIIB fractures was therefore 10%. These patients were excluded when considering the overall results.

The incidence of early perioperative complications was recorded on a database at the time of discharge. Patients with isolated tibial fractures were discharged when mobile on crutches with evidence of satisfactory wound healing. Patients were advised to remain nonweightbearing for the first 6 weeks after the injury, irrespective of the fracture configuration. Patients with multiple injuries were mobilized and discharge as rapidly as other injuries allowed. In 62 patients with isolated tibial fractures, the median duration of hospital stay was 7 days.

When possible, patients were examined on a monthly basis clinically and radiographically. Excluding the 2 patients who required amputations, there were 106 patients with 110 fractures with adequate followup. Eighty-six patients were examined by the authors. Seventeen patients who could not be examined locally were followed up by telephone interview and by contacting the local treating orthopaedic surgeon. At the time of followup, 3 patients had died of unrelated

medical causes. The outcome of these patients was assessed from data in clinical records.

Fracture union was assessed on the basis of clinical and radiographic criteria. A fracture was deemed to be united when the patient could fully bear weight with no pain at the fracture site and there was radiographic evidence of bridging of 3 of 4 cortices on standard anteroposterior and lateral views. Fractures that required revision intramedullary nailing or open bone grafting to achieve healing were designated nonunions. Fractures with bone loss that had elective bone grafting within 12 weeks of injury to bridge segmental defects after wound healing were not considered nonunions unless subsequent surgical intervention was required to achieve union. Dynamization of the nail was performed at the discretion of the treating surgeon and was not taken to be an indication of nonunion unless the fracture subsequently failed to heal.

Malunion was defined as any angulation in excess of 5° on radiographs, shortening in excess of 1 cm or rotational deformity in excess of 15° on clinical measurement in comparison with the normal side. Implant failure and any action required as a result was recorded. Deep infection was diagnosed in the presence of a purulent discharge necessitating further surgical debridement of infected bone or soft tissue.

The range of knee and ankle motion was recorded for each patient. Subtalar joint motion was compared with the contralateral side and designated as normal or reduced at the time of final followup. The patient's occupation and level of recreational activity were compared with the preinjury status. With regard to occupation, the patients were designated as being in the same occupation, changed, or unemployed. Similarly, recreational activity was defined as being the same, reduced, or nil as a result of the injury. The incidence of knee pain and necessity for implant removal also was recorded. The mean followup was 26 months (range, 12-83 months). Statistical analysis was done using the Mann-Whitney U-test and Kruskal-Wallis analysis of variance.

RESULTS

Early Postoperative Complications

Compartment syndrome complicated 8 (7%) fractures. Relating these cases to the Gustilo classification, there were 2 (6%) in Grade I fractures, 4 (10%) in Grade II fractures, and 1 (4%) in the Grade IIIA and 1 (6%) in the Grade IIIB fractures. The differences were not significant (Kruskal-Wallis analysis of variance; $p = 0.77$). In both of the Grade I open injuries, the diagnosis was made between 24 and 36 hours postoperatively. In 2 of the Grade II injuries and the Grade IIIB injury, there was clinical evidence of compartment syndrome at the time of presentation. This was confirmed before nailing by compartmental pressure monitoring, and a 4 compartment fasciotomy was performed as part of the initial surgical procedure. In the other 2 Grade II cases, the diagnosis was made on clinical grounds at 16 and 33 hours postoperatively, respectively. In the Grade IIIA injury, the diagnosis was made 21 hours postoperatively. The diagnosis was confirmed by pressure monitoring, and all patients subsequently had 4 compartment fasciotomies. Two patients had necrotic muscle in the anterior compartment and ultimately were required to use an ankle foot orthosis. The remaining patients had no sequelae attributable to the compartment syndrome. Fat embolus syndrome affected 3 (3%) patients. Two occurred in patients with multiple

long bone fractures. Nonfatal pulmonary emboli occurred in 2 patients (2%).

Union

Mean time to union was 29 weeks for Grade I fractures, 32 weeks for Grade II, and 34 weeks for Grade IIIA, and 39 weeks for Grade IIIB. These times included those fractures that went on to nonunion and required further intervention. Planned early bone grafting for segmental bony defects was required in 2 Grade IIIB fractures after soft tissue healing. Nonunion complicated 9 (8%) fractures, 1 (3%) Grade I fracture, 2 (5%) Grade II fractures, 3 (13%) Grade IIIA fractures, and 3 (17%) Grade IIIB fractures. The Grade I fracture nonunion was treated by revision nailing 45 weeks postinjury and healed within 16 weeks. Of the Grade II fracture nonunions, 1 was a proximal 1/3 fracture and the nail failed to provide adequate stability. The nail was removed and the fracture was plated 36 weeks postinjury. Union occurred 4 months later. The other nonunion was treated by revision nailing at 56 weeks and subsequently healed uneventfully.

Of 3 Grade IIIA fractures complicated by nonunion, all were dynamized between 18 and 26 weeks postinjury but failed to heal. All 3 had revision nailing without open bone grafting. Two healed within 4 months; the other has failed to heal but the patient has declined further surgery. Nonunion occurred in 3 Grade IIIB injuries. Two had bone grafting and revision nailing at 26 and 43 weeks, respectively. Both fractures healed. The remaining Grade IIIB nonunion occurred in association with an anterior defect that was bone grafted at 18 weeks and subsequently healed. Late bone grafting for nonunion therefore was required in 3 (3%) fractures of the series for aseptic nonunion.

Infection

Deep infection complicated 6 (5%) fractures. There were no early infective complications in Grade I open fractures. Four Grade II fractures (10%) were complicated by deep infection. Two patients presented within a month of the injury with purulent drainage from the fracture site. Long term antibiotic therapy was used, but the fractures failed to heal and purulent discharge persisted. Both fractures required exploration and bony debridement to eradicate the infection. both fractures were explored with nail removal and debridement of all infected bone. In 1 case, the nail was reinserted. In the other, the distal tip of the nail had broken through a screw hole and it could not be retrieved. Fixation therefore was done with a plate. Infection was eradicated, and in both cases, union subsequently occurred. In the remaining 2 cases, infection presented at 7 and 12 months postinjury at the site of the fracture. Debridement of the fracture site and revision nailing was performed. Both fractures have now healed with no sign of recurrent infection.

There were no infectious complications in Grade IIIA fractures. Of the 18 Grade IIIB fractures, deep infection occurred in 2 (11%). A 20-year-old man sustained 2 Grade IIIB open tibial fractures in a motorcycle accident. The defect was covered with a soleus flap at 7 days. The wound initially healed and the fracture appeared to be uniting uneventfully, but a sinus developed at the fracture site 9 months postinjury. Cultures were positive for Streptococcus. Implant removal and a sequestrectomy were performed. The fracture was judged to have healed, but he had a refracture 5 weeks later. This was treated with plating and bone grafting. The fracture

subsequently healed and he has had no recurrence of infection after 3 years of followup. The other Grade IIIB infection occurred in a 27-year-old man. At 3 days, the wound was covered with a soleus flap and split thickness skin graft. The soft tissues healed satisfactorily and the patient was discharged. Compliance was poor and the patient returned for followup 11 months postinjury. Radiographs revealed the proximal and distal interlocking screws had fractured and the fracture was ununited. There was no sign of infection and no action was taken. Four weeks later he presented with an abscess under the flap in communication with the fracture site. Radiographs revealed that the nail had broken at the site of the fracture. The abscess was drained, the fracture site and soft tissues debrided of infective material and after reaming of the canal a larger diameter nail was inserted. Antibiotic beads were left in the wound that was closed at 5 days. Bacteriology cultures were positive for Staphylococcus aureus. He was treated with intravenous cloxacillin for 14 days and oral therapy for a further 3 months, at which stage his fracture had healed with no sign of infection.

Malunion and Implant Failure

Screw breakage complicated 6 fractures (5%). Two of these cases were associated with a nonunion and 2 were associated with subsequent malunion. The other 2 screw fractures were noted coincidentally at the time of nail removal. There were 3 nail fractures (3%), 2 in association with the deep infection already detailed and the other in association with nonunion.

Malunion affected 7 (6%) fractures. It occurred in 2 (6%) Grade I fractures, 1 (3%) Grade II fracture, 3 (13%) Grade IIIB fractures, and 1 (5%) Grade IIIB fracture. Four of the malunions were caused by technical errors at the time of the original nailing procedure, leading to valgus or varus angulation at distal 1/3 fractures. Angulation was between 5° and 10° in 3 patients and 10° valgus in 1 patient. The latter patient is asymptomatic and has declined corrective osteotomy. Fixation failure was responsible for 2 malunions, 1 a proximal 1/3, and 1 a distal 1/3 fracture. Both healed with angulation between 5° and 10°, 1 valgus and 1 varus. One patient with a Grade IIIB fracture was treated for a nonunion by revision nailing and had the nail removed when the fracture was judged to be healed. He subsequently presented with an angular deformity. This required correction by slow distraction with an Ilizarov frame and renailing.

Functional Outcome

Joint range of motion was assessed in 86 patients with 90 fractures by the authors at the time of final followup. Restriction of knee motion was noted in 6 (7%) limbs. Loss of ankle motion was found in 13 (14%) limbs (Fig 1). Subtalar motion was reduced in 11 (12%) limbs. The incidence of ankle and subtalar joint stiffness was related to the severity of the original injury and was significantly higher in Grade IIIB injuries (Table 2). Troublesome knee pain after fracture healing affected 60 patients (57%). In 49 (46%) patients, the discomfort in relation to the nail was sufficient for implant removal to be performed. Refracture after nail removal occurred in 2 patients (4%) but, in 1 case, was associated with another significant fall while skiing.

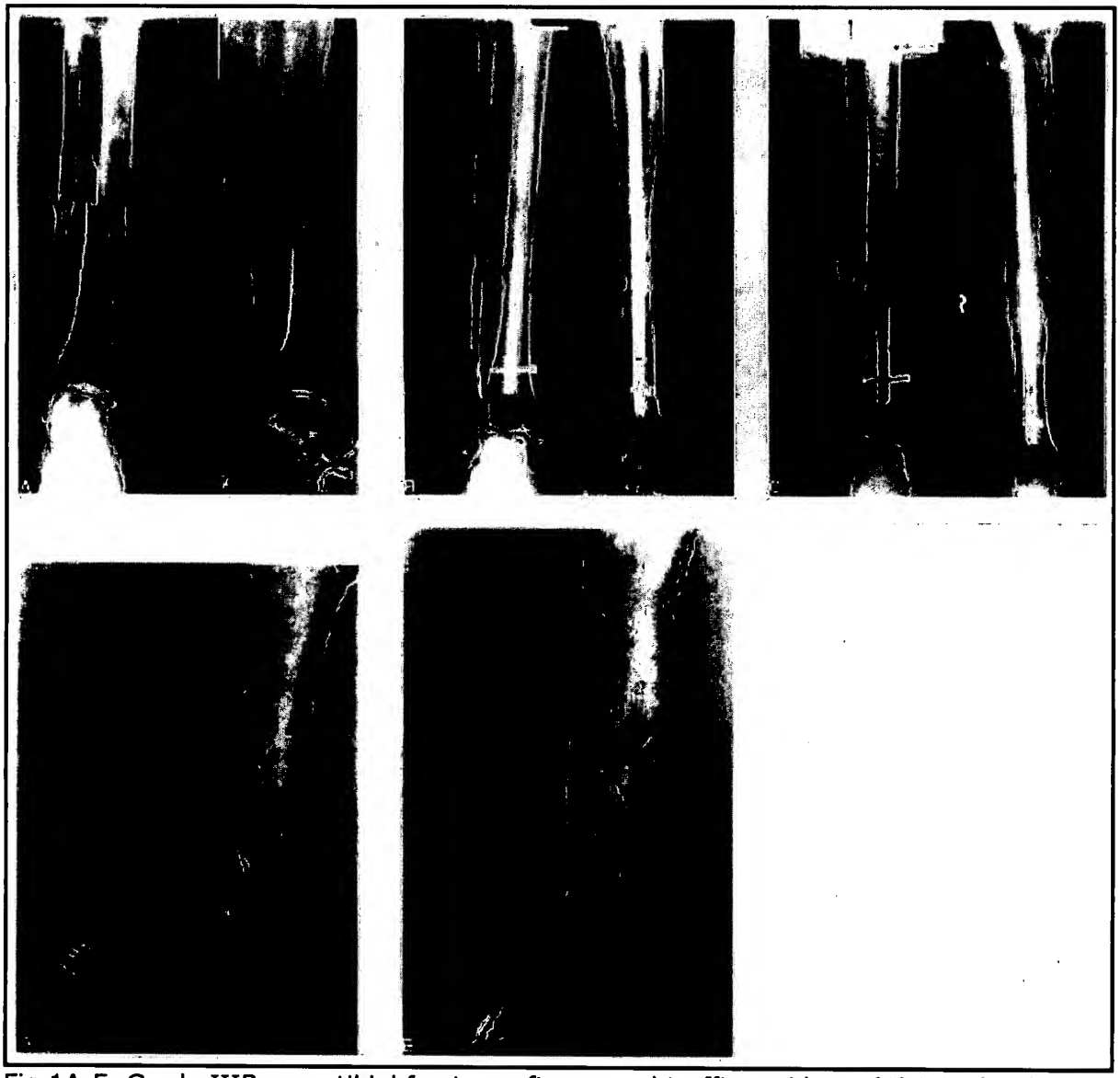

Fig 1A-E. Grade IIIB open tibial fracture after a road traffic accident: (A) initial radiographs, (B) two months after fixation, and (C) fracture completely united 6 months postinjury. Same patient at the time of final followup showing range of ankle motion: (D) dorsiflexion, and (E) plantar flexion.

Gustilo Grade	Ankle Stiffness [number (%)]	Subtalar Stiffness [number (%)]
I	1/25 (4)	1/25 (4)
II	5/29 (17)	4/29 (14)
IIIA	1/14 (7)	1/14 (7)
IIIB	6/19 (32)	5/19 (26)

TABLE 2. Incidence of Ankle and Subtalar Joint Stiffness Related to the Initial Soft Tissue Injury

At the time of followup, of 103 patients alive, 61 patients had returned to their original occupation. Sixteen patients had returned to a different form of employment or had been obliged

to retrain as a result of their injury. Nineteen patients were unemployed with no likelihood of returning to work as a consequence of disability secondary to the injuries sustained. The remaining 7 patients were retired before their injury. Fifty-three patients had returned to their former level of recreational activity; 37 had resumed a restricted level of recreation, and 13 considered themselves too disabled to resume any recreational activity. The capacity to return to normal occupational and recreational activity was closely related to the presence of multiple injuries. The median injury severity score was 12 for patients completely rehabilitated, 18 for those with restricted activity, and 23 for those patients who considered themselves completely disabled. These differences were statistically significant ($p < 0.004$ for occupation and 0.0005 for recreational rehabilitation; Mann-Whitney U test).

DISCUSSION

Open tibial fractures, particularly those with the more severe grades of soft tissue injury have been associated with high rates of malunion, nonunion, and deep infection. All modalities of fracture treatment have been used. The use of plaster casts to treat these fractures has been associated with an infection rate in excess of 15%[35] and malalignment rates as high as 70%.[5,35] These and other problems of cast treatment led to a brief period in which plating of open tibial fractures was in vogue. Although some studies reported good results, it soon became apparent that the technique was associated with an unacceptable rate of deep infection.[8,18,38] Other complications, including plate breakage and nonunion were frequent problems. In a prospective study comparing plating with external fixation of open tibial fractures, Bach and Hansen [1] reported a 19% deep infection rate in the plated group compared with 3% in the external fixation group.

These and other studies led to the adoption of external fixation as the treatment of choice for open tibial fractures. A couple of reports with modern designs [3,16] indicated good results could be obtained, even with the severe grades of soft tissue injury. Modern uniaxial frame designs have the benefit of simplicity and are less cumbersome than multiplanar frames such as the Hoffmann. However, a critical appraisal of the literature on the use of external fixation reveals consistent limitations, irrespective of frame design and configuration. There is a high rate of pin track sepsis and pin loosening. The requirement for bone grafting to achieve union is high, and some authors recommend routine bone grafting in the more severe injuries.[3,16] Maintaining an acceptable reduction of the fracture while awaiting the typically prolonged healing times for open tibial fractures is also a problem. Rates of malunion in excess of 20% are not unusual.[14,26]

Dissatisfaction with these limitations stimulated some authors to use intramedullary nailing. Velazco et al [44] reported the use of the Lottes nail in a series of 50 open tibial fractures and noted a 6% deep infection rate and a malunion rate of only 4%. In a study comparing Enders nailing with external fixation of open tibial fractures, Holbrook et al [23] noted an infection rate of 7% in the nailing group compared with 14% in the external fixation group. The malunion rate also was higher in the external fixation group (36% and 21%, respectively). Swanson et al [43] compared the Lottes nail with external fixation and reported infection rates of 6% in the nailing group and 7% in the external fixation group. The malunion rate was 27% and 24%, respectively. The principal drawback of these nails is their limited ability to stabilize comminuted fracture patterns properly or those fractures that are not in proximity to the isthmus of the tibia.

Locked nailing greatly increased the scope of intramedullary fixation in the treatment of tibial fractures, and they are now widely used for the management of closed tibial fractures. Although reamed nailing has been accepted as a method of choice for open femoral fractures, it is still a controversial method of treatment for open fractures of the tibia. The vascular damage inflicted by reaming in association with the soft tissue injury has been thought to increase the risk of infection and delayed union to unacceptable levels.10 Initial reports of the use of unlocked reamed nails for open tibial fractures were associated with a high infection rate.22,42 Consequently, reamed nailing has been considered to be contraindicated in the treatment of open tibial fractures.6,21,39

The literature on the use of reamed locking nails in the treatment of open tibial fractures is limited. The criticism that the technique is associated with a high rate of infection and nonunion largely is based on experimental evidence 28,37 and clinical reports with small numbers of patients for the most part treated with unlocked reamed nails.4,22,42 Recent evidence suggests that the reaming process is less harmful than generally has been supposed. Although reaming destroys the nutrient artery and injuries the endosteal surface, some studies suggest that the recovery time is rapid. Schemitsch et al 40 compared reamed and unreamed nailing in a rabbit fracture model and compared bone blood flow and callus strength. Although the reaming process was associated with an early decrease in blood flow, callus formation and strength were identical in both groups at 3 months. Reichert et al 36 studied the effects of reaming on bone blood flow in an intact sheep tibia. They found that reaming did not significantly alter cortical blood flow but that it was associated with a 6-fold increase in periosteal blood flow. They concluded that bone blood flow can be centripetal, and that the periosteal flow increase can compensate for the reaming damage to the endosteal circulation.

Several recent reports have suggested reamed locking nails may be used safely. Kaltenecker et al 24 reported on the use of locking nails to treat 66 Types I and II open tibial fractures and reported a 3.8% infection rate. Court-Brown et al 13 gave details of the use of the reamed Grosse-Kempf nail for 41 Grade II and Grade III open tibial fractures, reporting an infection in 1 of 14 Grade II and 3 of 13 Grade IIIB fractures. There were no infections in Grade IIIA injuries. The mean time to union was comparable with the results of external fixation in the same institution but the malunion rate and need for bone grafting were much lower.

Similar findings have been observed in the current study. The belief that reamed nailing would be associated with high rates of infection is not borne out by the results presented. An adequate soft tissue and bony debridement followed by sound soft tissue coverage is the key to minimizing deep infection in these injuries, irrespective of the type of fixation used. If infection occurs, it is not necessarily a catastrophic complication and usually can be eradicated if prompt bony debridement and revision of fixation are performed. These findings are in broad agreement with the experience of other authors who have studied the problem of infection after reamed locked intramedullary nailing of open tibial fractures.12,47 The addition of the bead pouch technique to the protocol in 1989 was associated with a subsequent reduction in the deep infection rate.25 The rather high rate of deep infection in the Grade II fractures is difficult to explain. However, differentiating these injuries from Grade IIIA fractures may be difficult even with considerable experience.7 It may be that numerous infected cases could have been considered Grade IIIA injuries at the outset, which would result in a lower infection rate for the Grade II injuries.

In addition to the low infection rate, other complications were lower in comparison with external fixation. The rate of late bone grafting to achieve union was only 3%, and the overall rate of malunion was 6%. These figures are considerably lower than those reported in association with the use of external fixation for these injuries. The most frequent complication in the current series was knee pain, which was also the most common reason for further surgical intervention.

It has been argued that the unreamed nailing would be safer than the reamed nail for open tibial fractures. Published experience with locking designs of unreamed nails has been limited. Whittle et al [45] reported on 50 open tibial shaft fractures treated with the unreamed locking nail with 4 (8%) deep infections, all in Grade III injuries. Locking screws broke in 10%, and there were 3 nail breakages. Singer and Kellam [41] reported on 43 open tibial fractures treated with unreamed nails. They noted a high complication rate, including a 12% rate of deep infection and locking screw breakage in 41%. Almost half of the fractures (47%) required further surgical intervention to achieve union. They concluded unreamed nails had no particular advantage over external fixation for open tibial fractures. In the only clinical study to date comparing reamed and unreamed nails,[27] no significant clinical difference was observed in terms of major complications. The only notable difference was an increased incidence of locking screw breakage in the unreamed nails, which had little influence on the outcome.

The results in the current study and other data support the view that reamed locked intramedullary nailing is a safe and effective technique for the management of open tibial fractures. It has the advantage over external fixation of being associated with a lower rate of malunion and need for bone grafting.

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Accession Number: 00003086-199705000-00025

Semiextended Position for Intramedullary Nailing of the Proximal Tibia.

Fracture

Clinical Orthopaedics & Related Research. 328:185-189, July 1996.
Tornetta, Paul III MD; Collins, Evan MD

Abstract:
Over a 24 month period, 30 patients with proximal tibia fractures who were reviewed consecutively were treated by nonreamed, statically locked, intramedullary nailing. There were 16 open, 13 segmental, and 7 comminuted fractures (Winquist III, IV). The average distance from the fracture to the proximal locking screws was 24 mm (range, 0-65 mm). All procedures were performed while the patient's affected leg was on a radiolucent table without traction. The last 25 fractures were nailed using a partial (2/3) medial parapatellar incision while the leg was semiextended. This approach allowed the patella to be subluxed laterally availing the trochlear groove for use as a conduit for nail placement. Using only 15 [degrees] knee flexion eliminated the extension force of the quadriceps on the proximal fragment, which otherwise would have tended to cause anterior angulation at the fracture site. In the first 5 patients, the average anterior angulation was 8 [degrees] (range, 5 [degrees]-15 [degrees]). Of the 25 patients who were treated while in the semiextended position, none had more than 5 [degrees] anterior angulation and 19 had no anterior angulation. Fractures of 3 of the 25 patients had greater than 5 [degrees] angulation in the coronal plane, 2 of which were nailed in the semiextended position. This technique greatly facilitates intramedullary nailing of proximal tibia fractures.

1: J Orthop Trauma. 2002 Nov-Dec;16(10):687-90.
Wolters Kluwer | Lippincott Williams & Wilkins

Incision placement for intramedullary tibial nailing: an anatomic study.

Althausen PL, Neiman R, Finkemeier CG, Olson SA.

University of California Davis Medical Center, Sacramento, California 95817, USA.

OBJECTIVES: For intramedullary nailing of tibial shaft fractures, a recent study has determined that the entry site should be just medial to the lateral tibial spine at the anterior margin of the articular surface. Gaining access to this site is often through a medial parapatellar or transpatellar approach. Several studies have indicated that a transpatellar approach may contribute to anterior knee pain. Our study sought to use anatomic measurement to determine the ideal incision site for insertion of an intramedullary tibial nail. DESIGN Part I: survey of Orthopaedic Trauma Association (OTA) members. Part II: anatomic study. SETTING: A Level I trauma center in Sacramento, California. PARTICIPANTS: Part I: OTA members. Part II: a group of 56 healthy volunteers. INTERVENTION: Part I: questionnaire sent to OTA members. Part II: clinical examination and radiographic analysis. MAIN OUTCOME MEASUREMENTS: Part I: responses to questionnaire. Part II: anatomic measurements. RESULTS: Part I: based on a questionnaire, OTA members use at least one or more approaches to access their preferred tibial nail entry site. Fifty-seven percent use only one type of approach in all cases. Part II: the authors performed a clinical and radiographic study in 56 volunteers (112 knees) to determine the relationship of the lateral tibial spine to the patellar tendon. On the basis of this information, the tendon was divided into thirds to account for the three most common surgical approaches. The entry site was in the lateral zone in 29 knees, the middle zone in 75 knees, and the medial zone in 8 knees. If divided equally into purely a medial or lateral zone to avoid a transpatellar approach, the starting point fell into the medial zone in 42 knees and the lateral zone in 70 knees. CONCLUSIONS: Individual variations in patellar tendon anatomy should be considered when choosing the proper entry site for tibial nailing. Based on the assumption that the ideal entry point for tibial nailing is just medial to the tibial spine at the anterior margin of the articular

surface, a preoperative fluoroscopic measurement before incision can guide the surgeon as to whether a medial parapatellar, transpatellar, or lateral parapatellar approach provides the most direct access to this entry site. The routine use of a single approach for all tibial nails may no longer be justified.

MeSH Terms:

- Adult
- Female
- Fracture Fixation, Intramedullary/methods*
- Humans
- Male
- Middle Aged
- Patella/anatomy & histology*
- Physician's Practice Patterns
- Questionnaires
- Tibial Fractures/surgery*

PMID: 12439190 [PubMed - indexed for MEDLINE]

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Set     Items   Description
S1        630   S AU=(COLE J? OR COLE, J?)
S2          3   S S1 AND TIBIA?
 ; show files
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[File 350] **Derwent WPIX** 1963-2007/UD=200738

**File 350: DWPI has been enhanced to extend content and functionality of the database. For more info, visit http://www.dialog.com/dwpi/.*

[File 347] **JAPIO** Dec 1976-2006/Dec(Updated 070403)

2/5/1 (Item 1 from file: 350) **Links**
Derwent WPIX

0016688339 *Drawing available*
WPI Acc no: 2007-403422/200738
XRPX Acc No: N2007-303123
Intramedullary nail e.g. trochanteric entry nail, for use in medullary canal of e.g. human tibia, has body with two walls defining two respective openings including related centerlines that are oblique with respect to each other
Patent Assignee: COLE J D (COLE-I); CZARTOSKI T J (CZAR-I); DAVISON D G (DAVI-I); MOED B R (MOED-I); MUHAMMAD W (MUHA-I); WATSON T J (WATS-I); WICH M K (WICH-I)
Inventor: **COLE J D**; CZARTOSKI T J; DAVISON D G; MOED B R; MUHAMMAD W; WATSON T J; WICH M K

Patent Family (1 patents, 1 countries)

Patent Number	Kind	Date	Application Number	Kind	Date	Update	Type
US 20070123873	A1	20070531	US 2005262654	A	20051031	200738	B

Priority Applications (no., kind, date): US 2005262654 A 20051031

Patent Details

Patent Number	Kind	Lan	Pgs	Draw	Filing Notes
US 20070123873	A1	EN	58	35	

Alerting Abstract US A1
NOVELTY - The nail (20) has a body defining a longitudinal axis (22) of the body, where an external periphery (24) of the body is defined for fitting in a medullary canal (2) of a long bone (4). The body has two internal walls (26, 30) defining two respective openings (28, 32) through the body, where each opening defines related opening centerlines (34, 36). The centerlines are oblique with respect to each other. The axis and the centerline (34) form an acute angle between the axis and the centerline (34). The axis and the centerline (36) form an acute angle between the axis and the centerline (36).

DESCRIPTION - An INDEPENDENT CLAIM is also included for a method of performing a trauma surgery on a long bone.
USE - Used in an intramedullary nail assembly or a kit, in a medullary canal of a long bone e.g. femur, **tibia**, and humerus, of a human, and for performing a trauma surgery on the long bone (claimed) that is fractured during an accident e.g. automobile accident.
ADVANTAGE - The provision of the openings allows for locking screws to be placed in various positions of the nail, so that the nail is locked using a combination of screws, and hence allowing for various locking constructions. The nail allows two separate screws to be placed through the nail, thus allowing better stability to be achieved with the locking screws. The design of the nail allows for multiple screw fixation to be achieved in opposing planes for better fracture stabilization, and facilitates proper and rapid healing for the fractured bones.
DESCRIPTION OF DRAWINGS - The drawing shows a partial anterior/posterior view of an intramedullary nail assembly.
2 Medullary canal
3 Neck
4 Long bone
6 Cortical bone
8 Cancellous bone
10 Intramedullary nail assembly
20 Intramedullary nail
22 Longitudinal axis
24 External periphery
26, 30 Internal walls
28, 32 Openings
34, 36 Opening centerlines
38, 58 Screws
40 Shank portion
42 Head
44 Greater trochanter
46 Lesser trochanter
48 Proximal portion
50 Distal portion
54 Longitudinal centerline of proximal portion
56 Longitudinal centerline of distal portion
60 Shank
62 Head
64 Cancellous threads
66 Cannula

Title Terms /Index Terms/Additional Words: INTRAMEDULLARY; NAIL; TROCHANTER; ENTER; MEDULLARY; CANAL; HUMAN; **TIBIA**; BODY; TWO; WALL; DEFINE; RESPECTIVE; OPEN; RELATED; OBLIQUE; RESPECT

Class Codes

International Patent Classification

IPC	Class Level	Scope	Position	Status	Version Date
A61F-0002/30	A	I	F	B	20060101
A61F-0002/30	C	I		B	20060101

US Classification, Issued: 606062000

File Segment: EngPI; ;
DWPI Class: P32

2/5/2 (Item 2 from file: 350) **Links**
Derwent WPIX

0014651410 *Drawing available*
WPI Acc no: 2004-833429/200482
XRPX Acc No: N2004-658707
Percutaneous-fixator insertion method for tibia fixator, involves s gaining supra patella surgical access to intramedullary canal of tibia proximal end, before inserting tibia fixator into proximal end of intramedullary canal
Patent Assignee: COLE J D (COLE-I)
Inventor: **COLE J D**

Patent Family (1 patents, 1 countries)

Patent Number	Kind	Date	Application Number	Kind	Date	Update	Type
US 20040243138	A1	20041202	US 2003454826	P	20030314	200482	B
			US 2004799179	A	20040312		

Priority Applications (no., kind, date): US 2003454826 P 20030314; US 2004799179 A 20040312

Patent Details

Patent Number	Kind	Lan	Pgs	Draw	Filing Notes	
US 20040243138	A1	EN	11	9	Related to Provisional	US 2003454826

Alerting Abstract US A1
NOVELTY - The method involves gaining a supra patella surgical access to an intramedullary canal of the proximal end of a **tibia** (T), before moving a **tibia** fixator posterior to a patella (P). The **tibia** fixator is inserted into the proximal end of intramedullary canal.
DESCRIPTION - INDEPENDENT CLAIMS are also included for the following:

a. a protective sheath; and
b. a **tibia** fixator insertion tool; and
c. a **tibia** fixator.

USE - For inserting **tibia** fixator used in fixing **tibia** proximal end.
ADVANTAGE - Simplifies and ensures reliable insertion of **tibia** fixator.
DESCRIPTION OF DRAWINGS - The figure shows the side view of the human knee joint with supra patella insertion of protective sheath.
30 Protective sheath
34 Distal end
F Femur
P Patella
T **Tibia**

Title Terms /Index Terms/Additional Words: PERCUTANEOUS; FIX; INSERT; METHOD; **TIBIA**; GAIN; PATELLA; SURGICAL; ACCESS; INTRAMEDULLARY; CANAL; PROXIMITY; END

Class Codes

International Patent Classification

IPC	Class Level	Scope	Position	Status	Version Date
A61B-017/58			Main		"Version 7"

US Classification, Issued: 606099000

File Segment: EngPI; ;
DWPI Class: P31

2/5/3 (Item 3 from file: 350) **Links**
Derwent WPIX

0013880468
WPI Acc no: 2004-059358/200406
XRAM Acc no: C2004-024342
Bone graft substitute composition kit useful as filter for voids or defects defined by bone, comprises mixture containing calcium sulfate hemihydrate, calcium sulfate dihydrate, and binder, and aqueous mixing solution
Patent Assignee: COLE J (COLE-I); SMITH T (SMIT-I); WRIGHT MEDICAL TECHNOLOGY INC (WRIG-N)
Inventor: **COLE J**; SMITH T

Patent Family (5 patents, 102 countries)

Patent Number	Kind	Date	Application Number	Kind	Date	Update	Type
US 20030185903	A1	20031002	US 2002368924	P	20020329	200406	B
			US 2003402192	A	20030328		
WO 2003082158	A1	20031009	WO 2003US9715	A	20030328	200406	E
AU 2003258172	A1	20031013	AU 2003258172	A	20030328	200435	E
EP 1489998	A1	20041229	EP 2003745668	A	20030328	200502	E

			WO 2003US9715	A	20030328		
US 7211266	B2	20070501	US 2003402192	A	20030328	200730	E

Priority Applications (no., kind, date): US 2002368924 P 20020329; US 2003402192 A 20030328

Patent Details

Patent Number	Kind	Lan	Pgs	Draw	Filing Notes	
US 20030185903	A1	EN	4	0	Related to Provisional	US 2002368924
WO 2003082158	A1	EN				
National Designated States,Original	AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NI NO NZ OM PH PL PT RO RU SC SD SE SG SK SL TJ TM TN TR TT TZ UA UG US UZ VC VN YU ZA ZM ZW					
Regional Designated States,Original	AT BE BG CH CY CZ DE DK EA EE ES FI FR GB GH GM GR HU IE IT KE LS LU MC MW MZ NL OA PT RO SD SE SI SK SL SZ TR TZ UG ZM ZW					
AU 2003258172	A1	EN			Based on OPI patent	WO 2003082158
EP 1489998	A1	EN			PCT Application	WO 2003US9715
					Based on OPI patent	WO 2003082158
Regional Designated States,Original	AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LI LT LU LV MC MK NL PT RO SE SI SK TR					

Alerting Abstract US A1

NOVELTY - Bone graft substitute composition kit comprises a mixture containing calcium sulfate hemihydrate, calcium sulfate dihydrate and binder, and an aqueous mixing solution.

DESCRIPTION - An INDEPENDENT CLAIM is included for production of the bone graft substitute composition which comprises contacting the mixture with saline solution.

ACTIVITY - Osteopathic.

MECHANISM OF ACTION - None given.

USE - Useful as filter for voids or defects defined by bone. It can also be used for intraoperative support of hardware, e.g. orthopedic hardware, e.g. bone plates, distal radium hardware and hardware used for **tibial** plateau fractures.

ADVANTAGE - The composition is capable of setting, e.g. *in vivo* in a short period to high hardness. It can promote bone growth.

Title Terms /Index Terms/Additional Words: BONE; GRAFT; SUBSTITUTE; COMPOSITION; KIT; USEFUL; FILTER; VOID; DEFECT; DEFINE; COMPRISE; MIXTURE; CONTAIN; CALCIUM; SULPHATE; BIND; AQUEOUS; MIX; SOLUTION

Class Codes

International Patent Classification

Class

	Level				
IPC		**Scope**	**Position**	**Status**	**Version Date**
A61K-0033/06	A	I		R	20060101

A61L-0024/00	A	I		R	20060101
A61L-0024/02	A	I		R	20060101
A61L-0027/02	A	I		R	20060101
A61L-0027/50	A	I		R	20060101
A61K-0009/00	A	I	F	B	20060101
A61K-0033/06	C	I		R	20060101
A61L-0024/00	C	I		R	20060101
A61L-0027/00	C	I		R	20060101
A61K-0009/00	C	I		B	20060101

US Classification, Issued: 424696000, 424400000, 424426000, 623023620, 623023510

File Segment: CPI; EngPI
DWPI Class: A96; B06; B07; D21; P32
Manual Codes (CPI/A-N): A12-V02; B04-C02A2; B04-C02D; B05-A01B; B05-C05; B14-N01; D09-C01D

?

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Set     Items   Description
S1       5200   S AU=(COLE J? OR COLE, J?)
S2         26   S S1 AND TIBIA?
S3         16   RD. (unique items)
 ; show files
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[File 155] **MEDLINE(R)** 1950-2007/Jun 18
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3/7/1 (Item 1 from file: 155) **Links**

Fulltext available through: USPTO Full Text Retrieval Options
MEDLINE(R)

23563516 **PMID:** 17515190
Effect of delayed treatment on open tibial shaft fractures.

Reuss Bryan L; **Cole J Dean**
Department of Orthopaedic Surgery, Orlando Regional Healthcare System, Orlando, Florida, 9512, USA. breuss@mac.com
American journal of orthopedics (Belle Mead, N.J.) (United States) Apr 2007 , 36 (4) p215-20 , **ISSN:** 1078-4519--Print **Journal Code:** 9502918
Publishing Model Print
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: In Process
Open **tibial** shaft fractures were analyzed retrospectively to determine the effect of treatment timing on infection and nonunion rates. The cases of 77 patients with 81 open **tibial** shaft fractures were reviewed. Patients were treated with initial wound cleansing and splinting in the emergency department and then formally with operative irrigation and debridement and stabilization, which included intramedullary (IM) nailing, external fixation, open reduction and internal fixation, or splinting. All **tibial** shaft components ultimately were treated with IM nailing. Mean time to operative treatment was 12.97 hours (SD, 10.8 hours). There were 7 infections (8.6%) and 3 nonunions (3.7%). Time was found not to be a significant factor in predicting either infection or nonunion. Increased severity of fracture was a significant factor in predicting infection rate. The infection rate for fractures treated first with external fixation and then with IM nailing was significantly higher than that for fractures treated with IM nailing alone. In addition, a relation was found between patients who received multiple debridements and development of infection. These results show that infection and nonunion rates were not adversely affected by longer time to operative treatment (up to 48 hours) when adequate trauma department open fracture care and early initiation of antibiotics were coupled with standardized and thorough debridement in the operative theater.
Record Date Created: 20070522

3/7/2 (Item 2 from file: 155) **Links**
Fulltext available through: USPTO Full Text Retrieval Options
MEDLINE(R)

15935839 **PMID:** 16424816
OPINION: Intramedullary nailing.

Cole J Dean
Journal of orthopaedic trauma (United States) Jan 2006 , 20 (1) p73-4 , **ISSN:** 0890-5339--Print **Journal Code:** 8807705
Publishing Model Print; Comment on J Orthop Trauma. 2006 Jan;20(1) 70-2; Comment on PMID 16424815
Document type: Case Reports; Comment; Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: MEDLINE; Completed

Record Date Created: 20060120
Record Date Completed: 20060525

3/7/3 (Item 3 from file: 155) **Links**
Fulltext available through: USPTO Full Text Retrieval Options
MEDLINE(R)

13539898 **PMID:** 11812486
The intramedullary skeletal kinetic distractor (ISKD): first clinical results of a new intramedullary nail for lengthening of the femur and tibia.

Cole J D; Justin D; Kasparis T; DeVlught D; Knobloch C
Injury (England) Dec 2001 , 32 Suppl 4 pSD129-39 , **ISSN:** 0020-1383--Print **Journal Code:** 0226040
Publishing Model Print
Document type: Clinical Trial; Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: MEDLINE; Completed
In 1986, a programme was initiated by the senior author to develop a reliable, mechanically activated, intramedullary lengthening device with a non-invasive means of measuring the progress of lengthening without X-ray. We report results of design, biomechanical testing, in vivo animal testing and clinical implantation of the first 20 intramedullary skeletal kinetic distractors (ISKDs) in adult patients with limb-length discrepancies.Twenty ISKD devices were implanted in 18 patients (14 males and four females). Lengthening was required due to infection (ten), trauma (six), polio (one) and burn (one). Six femurs and 14 **tibias** were lengthened. Mean patient age was 40 years (range, 18-65 years).No implant related infections, non-unions, malunions or joint contractures were observed. A design change was made following two initial hardware failures, after which there were no further breakages. Average lengthening was 49 mm (range, 29-110 mm). The average lengthening rate was 0.82 mm/day (range, 1.7-0.4 mm/day). Ability to work, walk and drive before, during and after treatment with the ISKD compared favourably with that of similar patients undergoing lengthening using the 'monorail' method in our practice.The ISKD appears to be a safe and cost-effective alternative to external fixators that reduces lifestyle disruption and complications during adult limb-lengthening procedures.
Record Date Created: 20020307
Record Date Completed: 20030507

3/7/5 (Item 5 from file: 155) **Links**
Fulltext available through: USPTO Full Text Retrieval Options
MEDLINE(R)

12995467 **PMID:** 11149501
Effect of acute reamed versus unreamed intramedullary nailing on compartment pressure when treating closed tibial shaft fractures: a randomized prospective study.

Nassif J M; Gorczyca J T; **Cole J K**; Pugh K J; Pienkowski D
Division of Orthopaedics, University of Kentucky, Lexington, USA.
Journal of orthopaedic trauma (United States) Nov 2000 , 14 (8) p554-8 , **ISSN:** 0890-5339--Print **Journal**

Code: 8807705
Publishing Model Print
Document type: Clinical Trial; Comparative Study; Journal Article; Randomized Controlled Trial
Languages: ENGLISH
Main Citation Owner: NLM
Record type: MEDLINE; Completed
OBJECTIVE: To compare anterior and deep posterior compartment pressures during reamed and unreamed intramedullary nailing of displaced, closed **tibial** shaft fractures. DESIGN: Randomized prospective study. SETTING: University Hospital/Level I trauma center. PATIENTS: Forty-eight adults with forty-nine fractures treated with intramedullary nailing within three days of injury. INTERVENTION: After intraoperative placement of compartment pressure monitors, the **tibia** fractures were treated by either unreamed intramedullary nailing or reamed intramedullary nailing. A fracture table and skeletal traction were not used in any of these procedures. MAIN OUTCOME MEASUREMENTS: Compartment pressures and deltaP ([diastolic blood pressure] - [compartment pressure]) were measured immediately preoperatively, intraoperatively, and for twenty-four hours postoperatively. RESULTS: Compartment syndrome did not occur in any patient. Peak average pressures were obtained during reaming in the reamed group (30.0 millimeters of mercury anterior compartment, 34.7 millimeters of mercury deep posterior compartment) and during nail insertion in the unreamed group (33.9 millimeters of mercury anterior compartment, 35.2 millimeters of mercury deep posterior compartment). The average pressures quickly returned to less than thirty millimeters of mercury and remained there for the duration of the study. The deep posterior compartment pressures were lower in the reamed group than in the unreamed group at ten, twelve, fourteen, sixteen, eighteen, twenty, twenty-two, and twenty-four hours postoperatively ($p < 0.05$ at each of these times. A statistically significant difference between anterior compartment pressures could not be shown with the numbers available. The deltaP values were greater than thirty millimeters of mercury at all times after nail insertion in both the reamed and unreamed groups. CONCLUSION: These data support acute (within three days of injury) reamed intramedullary nailing of closed, displaced **tibial** shaft fractures without the use of a fracture table.
Record Date Created: 20010108
Record Date Completed: 20010405

3/7/6 (Item 6 from file: 155) **Links**
Fulltext available through: USPTO Full Text Retrieval Options

12316244 **PMID:** 10052781
Two-staged delayed open reduction and internal fixation of severe pilon fractures.

Patterson M J; **Cole J D**
Orlando Regional Healthcare System, Florida 32804, USA.
Journal of orthopaedic trauma (UNITED STATES) Feb 1999 , 13 (2) p85-91 , **ISSN:** 0890-5339--Print
Journal Code: 8807705
Publishing Model Print; Comment in J Orthop Trauma. 2001 Nov;15(8) 591; Comment in PMID 11733681
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: MEDLINE; Completed
OBJECTIVE: To evaluate the use of a two-staged technique for the treatment of C3 pilon fractures. DESIGN: Retrospective. SETTING: Level I trauma center. PATIENTS/PARTICIPANTS: Twenty-one consecutive patients

with twenty-two C3 pilon fractures. Patients with C1 or C2 fractures and patients with open growth plates were excluded. INTERVENTION: All patients underwent immediate fibular fixation and placement of a medial spanning external fixator. After, on average, twenty-four days, patients underwent removal of the external fixator and formal open reduction and internal fixation of the pilon fractures. MAIN OUTCOME MEASUREMENTS: At average follow-up of twenty-two months, all patients were evaluated by using subjective, objective, and radiographic measurements as described by Burwell and Chamley (J Bone Joint Surg 1965;47B:634-659). Range of motion and postoperative complications were also recorded. RESULTS: Twenty-one of the twenty-two fractures healed within an average of 4.2 months. Average range of motion was 7 degrees of dorsiflexion, 33 degrees of plantar flexion, 17 degrees of eversion, and 11 degrees of inversion. Subjective and objective measurements showed 77 percent good results, 14 percent fair results, and 9 percent poor results. Radiographic reduction showed 73 percent anatomic and 27 percent fair reductions. There were no infections or soft tissue complications. The arthrodesis rate was 9 percent. CONCLUSIONS: A two-staged approach offers acceptable results for the treatment of severe pilon fractures. These results compare favorably with those of primary open reduction and of internal fixation and external fixation techniques. The major advantages include limited soft tissue complications and improved articular reconstruction.
Record Date Created: 19990429
Record Date Completed: 19990429

3/7/7 (Item 7 from file: 155) **Links**
Fulltext available through: custom link USPTO Full Text Retrieval Options
MEDLINE(R)

10540847 **PMID:** 7634691
A sequential protocol for management of severe open tibial fractures.

Cole J D; Ansel L J; Schwartzberg R
Matthews Orthopaedic Clinic, Orlando, FL 32856-2002, USA.
Clinical orthopaedics and related research (UNITED STATES) Jun 1995 , (315) p84-103 , **ISSN:** 0009-921X--Print **Journal Code:** 0075674
Publishing Model Print
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: MEDLINE; Completed
Fifty consecutive open fractures of the **tibia**, including 22 Grade IIIB and 4 Grade IIIC, were treated using a protocol of debridement, immediate wound coverage, and intramedullary nailing. Fasciocutaneous flaps were used extensively to cover areas of exposed bone. The severity of the soft tissue injury dictated the timing of definitive fixation. Fracture location determined implant selection and nailing technique. Patients were observed for an average of 21 months. Ninety-eight percent of the fractures united < 6 months postoperatively. There was 1 infection (2%), 2 malunions (4%), and 1 case of partial flap necrosis. Locking screws broke in 1 patient (2%); the fracture united with < 5 mm of shortening. Immediate postdebridement wound coverage, and intramedullary nailing after reconstruction of the soft tissue envelope facilitate fracture healing in these complex open injuries. Intramedullary nailing can be performed safely to include all grades of open **tibial** fractures from the proximal to distal metaphysis.
Record Date Created: 19950913
Record Date Completed: 19950913

3/7/8 (Item 8 from file: 155) **Links**
Fulltext available through: custom link USPTO Full Text Retrieval Options
MEDLINE(R)

10540817 **PMID:** 7634661
Mechanical failures of intramedullary tibial nails applied without reaming.

Hutson J J; Zych G A; **Cole J D**; Johnson K D; Ostermann P; Milne E L; Latta L
Department of Orthopaedics and Rehabilitation, University of Miami, FL, USA.
Clinical orthopaedics and related research (UNITED STATES) Jun 1995 , (315) p129-37 , **ISSN:** 0009-921X--Print **Journal Code:** 0075674
Publishing Model Print
Document type: Clinical Trial; Journal Article; Multicenter Study; Research Support, Non-U.S. Gov't
Languages: ENGLISH
Main Citation Owner: NLM
Record type: MEDLINE; Completed
The clinical mechanical failures of small diameter intramedullary interlocking nails were evaluated to determine the relationship of failure modes to the type or location of **tibial** fractures. Methods were developed to duplicate failure modes in vitro in standardized tests to simulate the clinical situations. Where standard test methods were inadequate, new methods were developed to provide quantifiable, reliable methods of evaluating potential clinical performance. The modes and rates of mechanical failure in the clinical series were consistent among participating centers: (1) In diaphyseal fractures with secondary trauma, the intramedullary nail bent at the fracture site where the working length was unsupported; (2) failures that occurred several weeks after nailing were the result of fatigue fractures of the locking screws, usually at the distal end; and (3) nail and screw failures occurred most commonly in proximal and distal **tibial** fractures. The strength of the 8- and 9-mm sizes of Synthes and Russell-Taylor nails were comparable.
Record Date Created: 19950913
Record Date Completed: 19950913

3/7/12 (Item 12 from file: 155) **Links**
Fulltext available through: USPTO Full Text Retrieval Options
MEDLINE(R)

07649656 **PMID:** 3333517
Current status of locked intramedullary nailing: a review.

Browner B D; **Cole J D**
Department of Surgery, University of Texas Health Science Center, Houston 77030.
Journal of orthopaedic trauma (UNITED STATES) 1987 , 1 (2) p183-95 , **ISSN:** 0890-5339--Print **Journal Code:** 8807705
Publishing Model Print
Document type: Journal Article; Review
Languages: ENGLISH
Main Citation Owner: NLM
Record type: MEDLINE; Completed
(59 Refs.)

Record Date Created: 19890324
Record Date Completed: 19890324

3/7/16 (Item 3 from file: 73) **Links**
Fulltext available through: USPTO Full Text Retrieval Options
EMBASE

05356238 **EMBASE No:** 1993124323
Open tibia fracture management: Protocol for acute coverage and intramedullary nailing

Cole J.D.
Matthews Orthopaedic Clinic,Orlando, FL United States
Journal of the Japanese Orthopaedic Association (J. JPN. ORTHOP. ASSOC.) (Japan) 1993 , 67/2 (S108)
CODEN: NSGZA **ISSN:** 0021-5325
Document Type: Journal ; Conference Paper
Language: ENGLISH

22/7/1 (Item 1 from file: 155) **Links**
Fulltext available through: USPTO Full Text Retrieval Options
MEDLINE(R)

14428769 **PMID:** 12887777
[Arthroscopic double-bundle posterior cruciate ligament reconstruction using quadriceps tendon-patellar bone autograft]

Feng Hua; Hong Lei; Wang Man-yi; Rong Guo-wei
Department of Orthopaedics and Traumatology, Beijing Jishuitan Hospital, Beijing 100035, China.
Zhonghua wai ke za zhi Chinese journal of surgery (China) Mar 2003 , 41 (3) p189-92 , **ISSN:** 0529-5815--Print
Journal Code: 0153611
Publishing Model Print
Document type: English Abstract; Journal Article
Languages: CHINESE
Main Citation Owner: NLM
Record type: MEDLINE; Completed
OBJECTIVE: To describe an alternative procedure of arthroscopic posterior cruciate ligament reconstruction using quadriceps tendon-patellar bone autograft and evaluate the early stage follow-up results. METHODS: Twenty consecutive cases of isolated and combined posterior cruciate ligament deficiency were studied. Quadriceps tendon with patellar bone block was used for preparation of Y-shaped autograft. Double femoral tunnels and single **tibial** tunnel were precisely **drilled** respectively at their anatomical footprint. By using this technique, the anterolateral bundle was fixed and tensioned in 90 degrees flexion, whereas the postero-medial bundle was fixed in full extension. In cases of combined injury, reconstruction or primary repair was conducted in one-stage or two-stage procedure. RESULTS: All cases were followed up for 6 months to 12 months, averaging 7.5 months. Lysholm rating scales and IKDC evaluation were used to make clinical subjective evaluations. Anteroposterior translation was measured with KT-1000 arthrometer and stress view radiography. Final Lysholm evaluation showed 5 patients (25%) were excellent, 14 (70%) good, and 1 (5%) poor. IKDC evaluation showed that 1 patient (5%) was graded as A, 16 (80%) as B, 2 (10%) as C and 1 (5%) as D. Stress view examination and KT-1000 arthrometer measurement showed that the average posterior translation improved from 11.5 mm and 11.0 mm preoperatively to 5.2 mm and 5.5 mm postoperatively.One patient was graded as failure. CONCLUSIONS: Arthrosopy assisted procedure of double-bundle posterior cruciate ligament reconstruction is effective and reproducible. The short follow-up clinical results are encouraging. Quadriceps tendon is an ideal autograft alternative for posterior cruciate ligament reconstruction.Combined posterior cruciate ligament injury, especially posterolateral complex insufficiency, should be early recognized and treated properly.
Record Date Created: 20030730
Record Date Completed: 20031030

22/7/9 (Item 9 from file: 155) **Links**
Fulltext available through: USPTO Full Text Retrieval Options
MEDLINE(R)

10723796 **PMID:** 8567130
[Treatment of posterior cruciate ligament rupture and recent knee dislocations by olecranisation of the patella without surgical repair]

Traitement des entorses posterieures et des luxations recentes du genou par olecranisation de la rotule sans reparation chirurgicale.
Rouvillain J L; Dib C; Bahuet F; Delattre O; Catonne Y
C.H.U. de la Meynard, Martinique, France.
International orthopaedics (GERMANY) 1995 , 19 (5) p269-74 , **ISSN:** 0341-2695--Print **Journal Code:** 7705431
Publishing Model Print
Document type: English Abstract; Journal Article
Languages: FRENCH
Main Citation Owner: NLM
Record type: MEDLINE; Completed
Olecranisation of the patella was described and first used by Grammont (1984) to maintain reduction of the knee joint after posterior cruciate repair and reconstruction. Since 1985 we used this technique in 18 acute posterior ruptures and knee dislocations which did not undergo surgery. Knee laxity is assessed under general anaesthesia with radiographic control. A 4 or 5 mm. Steinmann pin is introduced medially at the top of the patella and **drilled** vertically through the bone to continue **behind** the **patella** tendon. After reduction of the posterior drawer, the pin is passed into the anterior part of the **tibia**. Full mobility between 0 degrees and 90 degrees is maintained. Physiotherapy started immediately and early weight bearing is allowed with a posterior splint. Olecranisation prevents posterior subluxation of the **tibia** and gives an anterior **tibial** subluxation force which is minor in flexion but major in extension. We followed up our patients for 1 to 8 years. The latest testing with radiographs demonstrate posterior drawer but all patients report good results. Early physiotherapy avoids stiffness, amyotrophy, and reflex sympathetic dystrophy. Olecranisation appears to give similar results more quickly and with fewer complications than P. C. L. surgery.
Record Date Created: 19960306
Record Date Completed: 19960306

22/7/16 (Item 3 from file: 73) **Links**
EMBASE

00987021 **EMBASE No:** 1978115347
Semi cylindrical osteotomy of the upper end of the tibia. Technical modifications

OSTEOTOMIE SEMI CYCLINDRIQUE DE L'EXTREMITE SUPERIEURE DU **TIBIA**. MODIFICATIONS TECHNIQUES
Lang G.; Sejourne P.; Pointu J.; Kehr P.
Clin. Orthop., Hop. Chir. Orthop. Stephanie, Strasbourg France
Nouvelle Presse Medicale (NOUV. PRESSE MED.) (France) 1977 , 6/24 (2157-2159)
CODEN: NPMDA
Document Type: Journal
Language: FRENCH

Semi-cylindrical osteotomy of the upper end of the **tibia** offers the following advantages: 1) it does not change the length of the limb; 2) it requires no implantation; 3) it does not impair the musculo-ligamentous stability of the knee; 4) it allows the anterior tubercle of the **tibia** to be brought forward during the same session. Two Kirschner wires have to be inserted, one parallel to the articular cleft in the **tibial** epiphysis and the other metadiaphysially, at an

angle equal to the desired inclination. The osteotomy, which is perfectly cylindrical, is performed immediately **above** the **patellar** tendon. The two wires are made to parallel, and Charnley compressors are temporarily applied. Osteosynthesis with screw compression and plaster cast. The authors have devised a **guiding instrument** to facilitate the operation.(Castelllana - Trieste)

22/7/17 (Item 1 from file: 5) **Links**
Fulltext available through: ScienceDirect
Biosis Previews(R)

16284750 **Biosis No.:** 200100456589
Method for percutaneous intramedullary nailing of tibial shaft fractures

Author: Karladani Abbas (Reprint)
Author Address: 444 96 Odsmal, Pojkebo, Sweden**Sweden
Journal: Official Gazette of the United States Patent and Trademark Office Patents 1244 (4): Mar. 27, 2001 2001

Medium: e-file
ISSN: 0098-1133
Document Type: Patent
Record Type: Abstract
Language: English

Abstract: A method for percutaneous intramedullary nailing of **tibial** shaft fractures, intended to prevent anterior knee pain, comprising: placing a patient having at least one injured leg (1) in a supine position on a traction table; adjusting the leg so that the knee joint is flexed to approximately 90degree at a joint line (J); preparing and draping the leg; making an incision (6, 6') adjacently to the patella (4); creating a tunnel **behind** a **patellar** tendon of the injured leg, by means of a first **tool**, in a **direction** towards a **tibial** cortex of a **tibia** of the injured leg; penetrating the **tibial** cortex with a second tool; penetrating through the **tibial** cortex further into a medullary channel of the **tibia** (2) with a third tool; inserting an intramedullary nail into the medullary channel through the incision (6, 6'), wherein the incision (6, 6') is made medially or laterally to the patella (4) and perpendicularly to the joint line (J).

22/7/18 (Item 2 from file: 5) **Links**
Fulltext available through: ScienceDirect
Biosis Previews(R)

16201954 **Biosis No.:** 200100373793
Apparatus and method for creating a dome tibial osteotomy

Author: McAllister Craig M (Reprint)
Author Address: Kirkland, WA, USA**USA
Journal: Official Gazette of the United States Patent and Trademark Office Patents 1243 (3): Feb. 20, 2001 2001
Medium: e-file
ISSN: 0098-1133

Document Type: Patent
Record Type: Abstract
Language: English

Abstract: An instrument system and a method for creating a dome osteotomy having a semi-cylindrical surface contour configuration with an arcuate profile configuration at a selected location on a proximal **tibia** utilize a first guide component having a plurality of apertures placed along an arc which follows the arcuate profile configuration of the dome osteotomy and a **cannula** received in each aperture for establishing an array of parallel **drill** holes forming a pattern for the surface contour configuration of the dome osteotomy. A second guide component includes a slot which follows the arcuate profile configuration of the dome osteotomy and which is juxtaposed with the array of **drill** holes to guide osteotomes along the slot and into the **tibia** to create the surface contour configuration of the dome osteotomy. The osteotomes have a lateral curved configuration for following the arcuate profile configuration and footed osteotomes are used to reach **behind** the **patellar** tendon for completing the full dome osteotomy.